II.C.6.

FDA's point, which is not disputed by the comment, is that the discount and MSP programs discourage the planting of varieties that accumulate unusually low levels of nicotine.

FDA believes that it appropriately characterized the industry's role in the MSP's. The agency noted that the MSP's are administered by the USDA. *See* Jurisdictional Analysis, 60 FR 41697. In stating that the manufacturers exert control over the MSP's, the Agency did not imply that they exert sole control over all aspects of the programs. The manufacturers do, however, each have a vote on the MSP committees that set up the rules and administer the programs. They also represent by far the largest economic bloc on those committees.

4. The cigarette industry asserts that the cigarette manufacturers do not control the agronomic practices used by tobacco farmers for the purpose of increasing the nicotine content of tobacco. The comment maintains that all of the agronomic practices cited by the Agency as raising nicotine levels provide significant advantages to the farmer completely independent of any nicotine-enhancing properties. The comment also notes that some agronomic practices, such as irrigation, decrease nicotine content, and that recommendations regarding other practices, such as decreasing the use of nitrogen from the very high levels that were used for a few years, also result in decreased nicotine levels.

The Agency generally agrees with the comment on these points. The Agency never stated, and did not mean to imply, that cigarette manufacturers exert direct control over tobacco farmers or breeders. The Agency also agrees that farmers do not use nicotine-elevating agricultural practices exclusively for the purpose of elevating nicotine levels. The Agency is aware that farmers choose the agricultural practices they use for a

variety of purposes. Nevertheless, DeJong noted that "[h]eavy application of nitrogen fertilization, early topping and tight chemical sucker control all acted in concert to push alkaloid levels upward."[987]

In any case, the Agency's fundamental point regarding tobacco breeding and farming is that tobacco leaves sold in the U.S. contain adequate levels of nicotine to enable the manufacturers to maintain nicotine delivery in their products at the levels they choose. When, in the early and mid-1950's, farmers grew a preponderance of low-nicotine tobaccos, programs were set up to ensure that farmers would no longer grow such tobaccos. Since that time, manufacturers have had no difficulty purchasing tobaccos that provide the levels of nicotine that they need for their products. And in at least one well-documented case, Brown & Williamson doubled the nicotine content of one variety of flue-covered tobacco as a "blending tool" for use in low-tar cigarettes. This "Y-1" tobacco was designed to enable the company to maintain nicotine levels while lowering the tar content of cigarettes. *See* section II.C.3.c.iii., above.

vii. Comments on Leaf Purchasing.

1. The cigarette manufacturers assert that over time there has been no increase in the nicotine content of the tobacco they purchase. The manufacturers argue this is evidence that they do not use nicotine content as a principal factor in leaf selection.

The Agency disagrees with the manufacturers' factual assertion regarding trends in nicotine content. The evidence in the record indicates that the nicotine content has increased in the tobacco purchased by cigarette manufacturers. As pointed out in the

---

[987] *Id.*

Jurisdictional Analysis, the nicotine content in American tobaccos of all types has increased since the 1950's. 60 FR 41696–41697. Moreover, a 1978 article submitted by the Tobacco Institute and entitled "Genetic Manipulation for Tailoring the Tobacco Plant To Meet the Requirements of the Grower, Manufacturer, and Consumer" states that "*[i]n the United States the demand for lower stalk flue-cured tobacco has decreased.*"[988] This confirms the existence of a trend first described by USDA officials in congressional testimony in the late 1950's. *See* section II.C.4.a.i., above. At that time USDA indicated that the tobacco industry had "moved up the stalk" in blending tobaccos by using the higher nicotine leaves in the upper part of the tobacco plant.[989]

2. The cigarette manufacturers also assert that they have rejected high-nicotine tobaccos. Again, they claim that this is evidence that they do not use nicotine content as a principal factor in leaf selection.

The Agency disagrees with the manufacturers' argument. As noted above in section II.C.6.c.vi., the Agency recognizes that too much nicotine in a cigarette can make the cigarette too harsh.

3. In its comments, Brown & Williamson disputes that it regularly adjusts the stalk position of its leaf purchases during the buying season based upon the results of nicotine analyses. The company's response, however, conflicts with the information

[988] Chaplin JF, Genetic manipulation for tailoring the tobacco plant to meet the requirements of the grower, manufacturer, and consumer, *Bulletin D'Information Coresta* 1978;17-32, at 21 (emphasis added). *See* AR (Vol. 535 Ref. 96).

[989] *Hearings on False and Misleading Advertising (filter-tip cigarettes), Subcommittee on Government Operations, U.S. House of Representatives,* 85th Cong. 1st Sess. 189 (Jul. 1957). See AR (Vol. 172 Ref. 2035).

provided to FDA by company employees during FDA's May 1994 visit to Brown & Williamson. *See* Jurisdictional Analysis, 60 FR 41705. Moreover, Brown & Williamson provides no affidavits or other documentary evidence to support its comment.

viii. Comments on Reconstituted Tobacco.

1. The cigarette manufacturers assert that they do not use reconstituted tobacco to manipulate or control nicotine levels. As evidence of this point, they argue that nicotine levels in reconstituted tobacco are lower than those in most tobacco blends.

The Agency disagrees with the argument. Evidence in the record shows that reconstituted tobacco is used by cigarette manufacturers as a site for the addition of ammonia compounds. According to an article in the *Wall Street Journal,* an internal Brown & Williamson handbook describes the "nicotine pick-up potential" of ammonia in reconstituted tobacco.[990] The article also states that ammonia added to reconstituted tobacco can scavenge nicotine from the tobacco in the rest of the cigarette, significantly increasing the level of "free nicotine" in the cigarette.

2. The cigarette manufacturers assert that they do not closely monitor and control the level of nicotine in reconstituted tobacco.

The Agency disagrees with this assertion. The record shows that finished cigarettes contain precisely controlled and consistent nicotine levels. *See* Jurisdictional Analysis, 60 FR 41732. Because reconstituted tobacco is a significant ingredient in finished cigarettes, the precise control over nicotine in the finished cigarettes could not be

[990] Freedman AM, Tobacco firm shows how ammonia spurs delivery of nicotine, *Wall Street Journal* (Oct. 18, 1995), A1. *See* AR (Vol. 639 Ref. 2).

achieved unless the manufacturer also precisely controlled the nicotine level in reconstituted tobacco. Without such precise control, the wide variations in the nicotine levels of the tobacco stems and other raw ingredients of reconstituted tobacco would produce significant variations in the nicotine content of reconstituted tobacco and the finished cigarettes.

ix. Other Comments.

1. The Agency found in the Jurisdictional Analysis, based on the evidence then available, that cigarette manufacturers sometimes increase the degree to which the "tipping paper," which is wrapped around the filter, is extended over the tobacco rod. *See* 60 FR 41721. One study cited by the Agency reported that this increased "overwrap" reduced the nicotine deliveries reported by the FTC testing method (because the test protocol requires stopping the test when the cigarette is smoked to within 3 millimeters of the tipping paper), while allowing smokers to increase their nicotine intake above the reported levels (by smoking the tobacco under the overwrap).[991]

The manufacturers raise a number of questions about the data on which FDA relied and seek to depict FDA's discussion of the overwrap width as speculative. In most cases, however, the information that would answer the questions raised by the manufacturers is within their control, but is nevertheless not provided.

[991] Grunberg NE, Morse DE, Maycock VA, *et al.*, Changes in overwrap and butt length of American filter cigarettes, *NY State Journal of Medicine* Jul. 1985;310-312. *See* AR (Vol. 29 Ref. 478).

For example, the manufacturers argue that smokers do not smoke the overwrap because it is unpalatable, but they do not provide evidence to support this assertion despite the fact that the extensive consumer testing conducted by the manufacturers undoubtedly provides the information necessary to resolve whether the overwrap is smoked and whether it is palatable. The manufacturers also argue that the increase in overwrap width found in many cigarettes would not increase the amount of nicotine available to smokers if the burn rate of the cigarette were simultaneously increased. The burn rate of cigarettes is information known to the cigarette manufacturers but not to FDA. Yet the manufacturers fail to provide information on burn rate that would permit resolution of the issue they raise.

Moreover, although the manufacturers deny that the overwrap has been widened to increase availability of nicotine, they offer no alternative explanation for the increase found in the study relied on by FDA. In light of the ease with which the manufacturers could have provided the information necessary to show that the overwrap is not used to provide elasticity, and their failure to provide it, FDA concludes that the evidence supports the finding made in the Jurisdictional Analysis. Nevertheless, only additional information can help determine whether an increase in the tipping paper reduces the accuracy of the FTC measurement.

2. The cigarette manufacturers assert that the fact that they may hold patents permitting them to carefully manipulate and control nicotine does not prove that they actually do so. They also argue that patents are submitted by individual employees and that, as such, they are not evidence of the company's intentions.

II.C.6.

FDA cited the multitude of patents held by tobacco manufacturers on methods of manipulating nicotine delivery as additional evidence that the manufacturers have engaged in extensive research to develop methods to optimize nicotine delivery. The fact that the manufacturers have invested considerable resources in developing means of manipulating and controlling nicotine deliveries, including developing and acquiring patents, demonstrates that the manufacturers seek to be able to manipulate and control nicotine deliveries and have in fact "designed" and "planned" methods of doing so. This evidence is relevant to establishing the manufacturers' intentions. In light of the large number of patents held by the industry with the common goal of manipulating nicotine delivery, the argument that all of these patents were obtained by individual employees working without the direction of the manufacturers is not credible.

3. In the Jurisdictional Analysis, the Agency found that the failure of the cigarette manufacturers to remove nicotine from cigarettes was evidence that the manufacturers intend their products to provide the pharmacological effects of nicotine. *See* 60 FR 41779–41787. In their comments, however, the cigarette manufacturers assert that they do not have the capacity to manufacture an acceptable denicotinized cigarette and, even if they did, this would not establish that the manufacturers intend to affect the structure or function of the body.

In the Agency's view, the failure of denicotinized cigarettes in the marketplace is further evidence of the essential role of nicotine in cigarettes. The fact that efforts to introduce denicotinized cigarettes have failed demonstrates that consumers smoke cigarettes primarily to obtain the pharmacological effects of nicotine. Moreover, evidence that a manufacturer has, but does not use, technology that could remove a

pharmacologically active ingredient from its product is relevant evidence that the manufacturer intends that the product will have pharmacological effects upon consumers.

The manufacturers' assertion that denicotinized cigarettes have failed because of inadequacies in the denicotinizing technologies is not supported by the evidence in the record. To the contrary, the record contains abundant evidence that the reason a denicotinized cigarette will not succeed is because it fails to provide the pharmacological effects sought by consumers. For instance, an RJR document asserts that "*a zero nicotine cigarette . . . really has no potential to provide smoking satisfaction.* It produces no taste in the mouth, but even more seriously *it fails to provide the ultimate satisfaction in the lungs.*"[992]

4. The cigarette manufacturers argue that the evidence in the administrative record does not establish that they add "extraneous" nicotine to cigarettes. According to the manufacturers, the failure of the Agency to demonstrate that they add extraneous nicotine means that the Agency has not demonstrated that the manufacturers manipulate and control nicotine.

The Agency disagrees. The administrative record contains abundant evidence that tobacco manufacturers can manipulate and control nicotine deliveries without adding extraneous nicotine. The record before the Agency demonstrates that the manufacturers have developed and used many techniques to manipulate and control nicotine, and few of them involve the addition of extraneous nicotine. These techniques are discussed in detail in section II.C.4., above and include using nicotine-rich blends in low-yield cigarettes,

[992] Senkus M (R.J. Reynolds Tobacco Co.), *Some Effects of Smoking* (1976/1977), at 9 (emphasis added). *See* AR (Vol. 700 Ref. 593).

II.C.6.

using filtration and ventilation techniques that selectively remove more tar than nicotine, and chemical manipulation to increase free nicotine deliveries. All of these techniques manipulate and control nicotine deliveries; all of them facilitate consumer use of cigarettes for pharmacological purposes; and none of the techniques require the addition of extraneous nicotine.

## D. THE STATEMENTS, RESEARCH, AND ACTIONS OF THE SMOKELESS TOBACCO MANUFACTURERS SHOW THAT THE MANUFACTURERS INTEND THEIR PRODUCTS TO AFFECT THE STRUCTURE AND FUNCTION OF THE BODY

In sections II.A. and II.B., above, the Agency concluded that smokeless tobacco is "intended" to affect the structure and function of the body on the basis of the foreseeable pharmacological effects and uses of smokeless tobacco and its widespread actual use by consumers for pharmacological purposes. In this section, the Agency considers a third category of evidence of intended use: the statements, research, and actions of the smokeless tobacco manufacturers.

The administrative record includes considerable evidence of the smokeless tobacco manufacturers' statements, research, and manufacturing practices. Much of this evidence has only recently become available as the result of the Agency's investigation, congressional hearings, and other investigations and sources. As discussed in section II.C.1., above, this evidence of the statements, research, and actions of the manufacturers is part of the relevant objective evidence that the Agency may rely upon in determining a product's "intended uses." The Agency's role in making these determinations is that of a fact finder. The Agency's fact-finding task has been made more difficult by the manufacturers' general refusal to cooperate with the Agency's investigation. In particular, the manufacturers failed to provide FDA with information and documents requested by the Agency in July 1994 regarding the role of nicotine in smokeless tobacco.[993] This lack of cooperation has made the Agency's investigation more difficult. The limited number of company documents provided by the

[993] *See*, e.g., Letter from Chesemore RG (FDA) to Gierer V (U.S. Tobacco Company) Jul. 19, 1994. *See* AR (Vol. 54 Ref. 619).